K090586

510(k) SUMMARY (As Required per 21 CFR 807.92(c))

GENERAL INFORMATION:

AUG 07 2009

510k Owner's Name **Address**	Bovie Medical 3200 Tyrone Boulevard, Suite A St. Petersburg, Florida 33710-2902
Contact Person	Richard A. Kozloff Vice-President; Quality Assurance/Regulatory Affairs Telephone #: (727) 803-8513 FAX Number: (727) 347-9144
Date Prepared:	July 1, 2009

DEVICE DESCRIPTION:

Trade Name:

Bovie ICON GS General Purpose Electrosurgical Generator, Accessory Cable and Handpiece

Common Name:

Electrosurgical Generator

Classification Name:

Electrosurgical Cutting and Coagulation Devices and Accessories (21CFR 878.4400; Class II; Product Code GEI)

Predicate Devices:

Tenerco, Inc. Helica TC Thermo Coagulator	(K972267)
Plasma Surgical Ltd. PlasmaJet System	(K030819)

510(k) SUMMARY (As Required per 21 CFR 807.92(c))

DEVICE OPERATION:

The Bovie ICON GS (the **Generator)** operates by utilizing high frequency radiofrequency (RF) energy to create an ionized gas plasma channel which, when used in conjunction with the handpiece accessory, is used coagulate tissues. The plasma output is comparable between the generator and predicate device.

The **Generator** has an RF mode of operation that can vary the output intensity, duty cycle and Helium gas flow to control the coagulation intensity.

The generator is designed to comply with applicable Medical Electrical Equipment safety standards, including electromagnetic compatibility and other safety standards.

The Generator uses technology substantially equivalent to the predicate devices. The generator incorporates an ergonomically designed user interface screen for the selection of device settings. Although different from the user interface of the predicate devices, the difference does not affect the safety and effectiveness and may provide improved visualization of the device settings.

The **Handpiece** is a single use device designed to only be compatible with the ICON GS generator and cable. This handpiece contains a programmable memory device that requires a unique code for the generator to operate. The handpiece has a button for finger activation of the generator. Once activated, helium gas flows out the tip of the device and is excited by the high electric field resulting in a plasma flame.

There are no new hazards presented with the use of the Bovie ICON GS generator and handpiece as compared with the named predicate device.

INTENDED USE:

"The Bovie ICON GS system is an electrosurgical device that utilizes Helium gas for the coagulation of soft tissues during open soft tissue surgery."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 07 2009

Bovie Medical
% Mr. Richard Kozloff
Vice-President, Quality Assurance and Regulatory Affairs
7100 30th Avenue North
Saint Petersburg, Florida 33710-2902

Re: K090586
Trade/Device Name: Bovie ICON GS Generator and Handpiece
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: July 1, 2009
Received: July 2, 2009

Dear Mr. Kozloff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Bovie ICON GS Generator and Handpiece

Indications for Use:

"The Bovie ICON GS system is an electrosurgical device that utilizes Helium gas for the coagulation of soft tissues during open soft tissue surgery."

Prescription Use ✓ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090586